## Semaglutide (WEGOVY) Subcutaneous Injection Criteria for Use September 2021

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

For patients prescribed semaglutide (OZEMPIC) for the management of type 2 diabetes mellitus, please consult the Semaglutide (OZEMPIC) Criteria for Use. The Semaglutide (WEGOVY) Criteria for Use apply to the use of semaglutide as a medication for chronic weight management.

Exclusion Criteria		
		answer to ANY item below is met, then the patient should NOT receive semaglutide (WEGOVY) for chronic ight management.
		Pregnancy ^1
		Type 1 diabetes
		Personal or family history of medullary thyroid carcinoma or with Multiple Endocrine Neoplasia syndrome type 2
		Severe gastrointestinal dysmotility, including gastroparesis
		History of pancreatitis (does not pertain to patients for whom the cause of pancreatitis is known and no longer presents a risk) ^2
		The patient has a history of suicidal attempts or active suicidal ideation ^3 (unless a mental health consultation supports benefits of semaglutide in a patient with a history of suicide attempts or recent suicidal ideation)
		Concurrent use of another medication FDA approved for weight loss
		Veight loss offers no potential benefit to a pregnant patient and may result in fetal harm; refer to product information isk factors include triglyceride level > 1000 mg/dL, known gallstones with intact gallbladder, alcohol abuse
		er clinical trial exclusion criteria (lifetime history of suicidal attempt, recent suicidal behavior or ideation) and varnings/precautions in product information
Inclusion Criteria		
	The a	inswers to ALL of the following must be fulfilled in order to meet criteria for semaglutide (WEGOVY).
		Verifiable participation in a comprehensive lifestyle intervention that targets all three aspects of weight management: diet, physical activity, behavioral changes ^4
		BMI is greater than or equal to 30 kg/m $^2$ <b>OR</b> BMI is greater than or equal to 27 kg/m $^2$ with at least one weight-related comorbidity $^5$
		Medication regimen has been reviewed to identify and discontinue medications associated with weight gain when clinically safe and appropriate ^4
For patients who can become pregnant:		

Pregnancy should be excluded prior to receiving semaglutide (WEGOVY) and the patient provided

contraceptive counseling on potential risks vs. benefits of taking semaglutide (WEGOVY) if patient were to

become pregnant

- 4. Refer to PBM-MAP-VPE Clinical Guidance: Weight Management Medications for Chronic Use Guidance for Treatment Selection
- 5. Examples of weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, obstructive sleep apnea, osteoarthritis, nonalcoholic fatty liver disease

## **Additional Inclusion Criteria**

The answer to ONE of the following must be fulfilled in order to meet criteria for semaglutide (WEGOVY).
 Patient has an inadequate response, ^6 contraindication or intolerance to at least two VA National Formulary agents for chronic weight management ^7
 Patient with BMI >= 40 OR BMI 35 to < 40 with a significant or difficult to manage weight-related condition ^8 or is unable to achieve weight loss goals required for surgery ^9</li>
 Patient has type 2 diabetes treated with semaglutide (OZEMPIC) AND requires additional weight loss to achieve >=5% reduction in initial body weight ^10

- 6. e.g., < 5% reduction in body weight
- 7. e.g., phentermine/topiramate; naltrexone/bupropion; orlistat
- 8. e.g., severe sleep apnea documented by sleep study; disability due to osteoarthritis; nonalcoholic steatohepatitis with objective evidence of fibrosis (Stage >=F2); potential candidate for bariatric surgery; etc
- 9. e.g., surgery for obesity related condition, general surgery
- 10. Weight loss occurs with the GLP-1 agonist class. In addition, it is unknown if use of semaglutide (WEGOVY) in patients with overweight or obesity offers the same cardiovascular (CV) outcome benefit as semaglutide 1.0 mg (OZEMPIC) injection, or liraglutide 1.8 mg (VICTOZA) injection, in patients with diabetes and pre-existing CV disease